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## <u>VIA CERTIFIED MAIL</u> RETURN RECEIPT REQUESTED

October 28, 1999

NECESTA 199

Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C St., S.W. Washington, DC 20204

Dear Sir or Madam:

This notification is being filed pursuant to section 403(r)(6) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 343(r)(6), and in accordance with the requirements of 21 C.F.R.§ 101.93. Scientific Hospital Supplies North America, Inc., 9600 Medical Center Dr., Rockville, Maryland 20850, plans to market a dietary supplement bearing the following statements on the label and/or in the labeling:

Name of supplement:

MyoVive™

Dietary ingredients that are the subject of

are the subject of structure/function

statements:

Coenzyme q10

Creatine Cysteine

Folic Acid L-carnitine Potassium Selenium

Taurine
Thiamin
Vitamin A
Vitamin B6
Vitamin B12
Vitamin C
Vitamin E

## Structure/function statements:

- 1. Cardiac dietary supplement —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 2. For your heart —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 3. Energize —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 4. Replete —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 5. Support —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 6. Protect —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.
- 7. Helps to keep you and your heart healthy, energetic and active —This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Coenzyme q10, L-carnitine, Potassium, Taurine, Vitamin E, Folic Acid, Thiamin, Vitamin B6, and Vitamin B12.

- 8. Contains I-carnitine, coenzyme q10 and taurine to promote cardiac muscle cell performance—This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients L-carnitine, Coenzyme q10 and Taurine.
- 9. Contains creatine, l-carnitine and taurine to promote body muscle cell performance—This statement is the subject of MyoVive™, which contains 33 active ingredients, and the specific ingredients Creatine, L-carnitine and Taurine.
- 10. Contains 5 effective anti-oxidants to protect against oxidative stress—This statement is the subject of MyoVive™, which contains 33 active ingredients, including Cysteine, Vitamin A, Vitamin C, Vitamin E, and Selenium.

FDA has previously been notified of, and has permitted, statements identical or highly similar to the proposed statements for MyoVive™ and the specified MyoVive™ ingredients.

The undersigned certifies that the information presented and contained in this notification is complete and accurate, and that Scientific Hospital Supplies North America, Inc. has substantiation that each structure/function statement is truthful and not misleading.

Sincerely

Mark A. De Fries Chief Executive Officer